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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ELEY, JESSICA L	
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2884	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,568	KIMCHY ET AL.	
	Examiner	Art Unit	
	JESSICA L. ELEY	2884	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,15-32 and 46-54* is/are pending in the application.

4a) Of the above claim(s) *33-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,15-32 and 46-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/25/09, 03/04/09, 06/09/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The objection to claim 27 is hereby withdrawn in view of the amendment filed 04 March 2009.

2. The rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is hereby withdrawn in view of the amendment filed 04 March 2009.

3. Applicant's arguments with respect to claims 1-7 and 15-32 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 4th of March 2009 have been fully considered but they are not persuasive. Applicant argues that Liebig does not teach an *attenuation-instruction generator* configured to compute a set of attenuation instructions for said first image, based at least on *non-uniformities* in said second, structural image. This argument is not persuasive, Liebig clearly discloses that the attenuation of radiation is non-uniform because the attenuation coefficients of different tissues and bone are different, however these non-uniformities may be compensated for by generating an "attenuation map" of the body using well-known methods and procedures (Column 4 lines 1-30).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 53 is rejected under 35 U.S.C. 102(b) as being anticipated by **Liebig et al US 5,672,877 (henceforth referred to as Liebig)**.

Regarding **claim 53,** Liebig teaches a method of reconstructing a 3D radiation image (C5 L30-33), comprising:

Collecting ionizing radiation that exits from a tissue (C6 L52-55);

Imaging said tissue using non-ionizing radiation (step **802**);

Identifying tissue boundaries in said non-ionizing radiation image (C10 L39-45); and

Reconstructing an ionizing radiation image from said collected radiation using said tissue boundary identifications (steps **804** and **806**).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. **Claims 1-3, 5-7, 18, 22, 27-30, 46-52, and 54** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Liebig et al US 5,672,877 (henceforth referred to as Liebig)**.

Regarding **claim 1**, Liebig teaches an imaging apparatus, comprising:

A first device which, obtains a first image, by a first modality, said image being an ionizing radiation image (gamma camera, C4 L29-34), wherein said first image is registered to a system of coordinates;

A second device which obtains a second structural image, by a second modality, "other modality" (C4 L34); and

A computerized system **112**, which comprises;

A registrator for co-registering said second, structural image to said system of coordinates (C10 L31-63), and

an attenuation-instruction generator configured to compute a set of attenuation instructions for said first image, based at least on non-uniformities in said second, structural image (Column 4 lines 1-30).

Liebig does not specifically teach the structural image being an ultrasonic image. However, Liebig does teach that the "other" modality should yield information about the anatomical structures surrounding the organ of interest and gives the examples of x-ray CT and MRI as devices that provide images of anatomical structures, such as the lungs and skeletal structures (C10 L36-45). Liebig also teaches that different image modalities included with CT is ultrasound imaging and fluoroscopy (C1 L13-16), each of which yields images having unique characteristics. It would be obvious to one of ordinary skill in the art at the time the invention was made to pursue the known options within his or her technical grasp if this leads to anticipated success. Thus the "other" modality could be ultrasound, since ultrasound imaging provides the anatomical structural information useful when co-registering image information using SPECT which provides little or no information about the surrounding anatomical structures (C10 L36-38).

Regarding **claim 2**, Liebig teaches the imaging apparatus of claim 1, wherein said computerized system is further configured to compute, based on said a set of attenuation instructions an attenuation-corrected image of said first image (column 4 lines 15-34).

Regarding **claim 3**, Liebig teaches the imaging apparatus of claim 2, wherein said computerized system is further configured to display a superposition of said attenuation-corrected first image and said second, structural image (column 11 lines 34-41).

Regarding **claims 5 and 6**, Liebig teaches the imaging apparatus of claim 1, wherein said registrator for coregistering said second, structural image to said system of coordinates relies on that said first and second devices share a single position-registration device (column 10 lines 54-58) and have substantially equal position-registration devices (column 10 lines 58-63), for co-registering said second, structural image to said system of coordinates.

Regarding **claim 7**, Liebig teaches the imaging apparatus of claim 1, wherein said registrator for coregistering said second, structural image to said system of coordinates relies on fiduciary marks (markers, column 2 lines 12-32) visible both on said first image and on said second, structural image, for co-registering said second, structural image to said system of coordinates.

Regarding **claims 18 and 22**, Liebig teaches the imaging apparatus of claim 1, but does not expressly teach the imaging apparatus designed to be inserted through a trucar valve or designed as a handheld, extracorporeal probe. However, Liebig does acknowledge that the technique of coregistered images may be applied to any types of views obtaining using medical imaging techniques such as a coronal views, etc. (column 12 lines 19-21). It would have been obvious to one of ordinary skill in the art at the time the invention was made to design the imaging apparatus to be inserted through a trucar valve or designed as a handheld extracorporeal probe, as a person of ordinary skill in the art has good reason to pursue the options within his or her technical grasp.

Regarding **claim 27**, Liebig teaches an imaging method, comprising:

Imaging by a first modality, a first image, by ionizing radiation such as SPECT, PET, CT, x-rays (column 10 lines 31-34);

Imaging by a second modality a second structural image, by a second modality, "other modality" (C4 L34); and

Computing a set of attenuation instructions for said first image, based at least on non-uniformities in said second, structural image (column 4 lines 15-34).

Liebig does not specifically teach the structural image being an ultrasonic image. However, Liebig does teach that the "other" modality should yield information about the anatomical structures surrounding the organ of interest and gives the examples of x-ray CT and MRI as devices that provide images of anatomical structures, such as the lungs and skeletal structures (C10 L36-45). Liebig also teaches that different image modalities included with CT is ultrasound imaging and fluoroscopy (C1 L13-16), each of which yields images having unique characteristics. It would be obvious to one of ordinary skill in the art at the time the invention was made to pursue the known options within his or her technical grasp if this leads to anticipated success. Thus the "other" modality could be ultrasound, since ultrasound imaging provides the anatomical structural information useful when co-registering image information using SPECT which provides little or no information about the surrounding anatomical structures (C10 L36-38).

Regarding **claim 28**, Liebig teaches the imaging method of claim 27, further comprising computing an attenuation-corrected first image based on said a set of attenuation instructions (column 4 lines 15-34).

Regarding **claims 29 and 30**, Liebig teaches the imaging method of claim 27, wherein said computerized system is further configured to display **806** a superposition of said attenuation-corrected first image and said second, structural image (column 11 lines 34-41).

Regarding **claims 46-48**, Liebig teaches an imaging apparatus according to claim 1, wherein said first modality is selected from a group consisting of SPECT, PET, CT (C10 L31-34), an extracorporeal gamma scan, C3 L57-62) and a combination thereof.

Regarding **claims 49 and 50**, Liebig teaches an imaging apparatus according to claim 1, wherein said generator generates said attenuation instructions based on an identification of boundaries between tissues, in said structural image; or tissues in said image according to tissue type (C4 L1-14).

Regarding **claim 51**, Liebig teaches an imaging apparatus according to claim 1, wherein said generator generates said attenuation instruction based on a 3D structural image (C5 L30-33).

Regarding **claim 52**, Liebig teaches an imaging apparatus according to claim 1, wherein said first device and said second device are mounted on an elongate element and occupy different axial locations (C5 L34-43).

Regarding **claim 54**, Liebig teaches a method according to claim 53, but does not teach the imaging comprises contacting an imaging probe against the body. However, Liebig does teach that the "other" modality should be on the yields information about the anatomical structures surrounding the organ of interest and gives the examples of x-ray CT and MRI as devices that provide images of anatomical structures, such as the lungs and skeletal structures (C10 L36-45). Liebig also teaches that different image modalities included with CT is ultrasound imaging, which requires an imaging probe contacting the body (C1 L13-16), which yields images having unique characteristics. It would be obvious to one of ordinary skill in the art at the time the invention was made to pursue the known options within his or her technical grasp if this leads to anticipated success. Thus the "other" modality could be ultrasound, since ultrasound

imaging provides the anatomical structural information useful when co-registering image information using SPECT which provides little or no information about the surrounding anatomical structures (C10 L36-38).

10. **Claims 4, 11, and 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Liebig** as applied to claim 3, 8 and 30 respectfully above, and further in view of **Front et al. US 6,368,331 B2 (henceforth referred to as Front)**.

Regarding **claims 4, 11, and 31**, Liebig teaches the imaging apparatus of claims 3 and 8 and the imaging method of claim 30, as discussed above, but does not a teach the apparatus further including an instrument, registered to said system of coordinates and visible on at least one of said first image and said second, structural image and wherein said computerized system is further configured to guide said instrument in-vivo, based on said superposition. Front teaches a medical imager that combines the image from a PET scanner and a CT or MRI while simultaneously guiding therapeutic instrument **520** using guide device **506** (FIG. 7). It would be obvious to one of ordinary skill in the art at the time the invention was made to use the therapeutic instrument and guide device taught by Front with the teachings of the coregistered medical image taught by Liebig, since Front teaches that there is a need for accessing a correct target region inside the patient's body with a diagnostic or therapeutic instrument (column 2 lines 46-49).

11. **Claims 15 and 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Liebig** as applied to claim 1 and 30 respectfully above, and further in view of **Fry et al. US 4,951,653 (henceforth referred to as Fry)**.

Regarding **claims 15 and 32**, Liebig teaches the imaging apparatus of claim 1 and the imaging method of claim 30, but does not specifically detail the embodiment further comprising an ultrasound transducer operative of focused ablation. Liebig does acknowledge that the technique of coregistered images may be applied to any types of views obtaining using medical imaging techniques (column 12 lines 19-21). Fry teaches an ultrasound brain lesioning system that uses transducer **29** for focused ablation (column 8 lines 14-19). The apparatus taught by Fry uses ultrasound, CT or MRI scans in order to obtain the feature data of a target, in this case a brain tumor, to accurately control the mechanical drive of the transducer (column 4 lines 18-21). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ultrasound transducer with the coordinate medical imaging taught by Liebig, as Liebig provides coregistered images from a variety of sources such as SPECT, CT and MRI, thus generating a more accurate scan data that Fry acknowledges is desirable with the ultrasound transducer (column 2 lines 2-10).

12. **Claims 16, 17, and 23-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Liebig** as applied to claim 1 above, and further in view of **Benaron et al. US 6,246,901 B1 (henceforth referred to as Benaron)**.

Regarding **claims 16 and 17,** the disclosure of Liebig teaches all of the limitations of the imaging apparatus of claim 1, as discussed above. Liebig does not directly disclose the scenario

of the imaging system is designed as a rectum probe, or as an endoscope probe; however such adaptations are common in the art. Liebig does acknowledge that the technique of coregistered images may be applied to any types of views obtaining using medical imaging techniques (column 12 lines 19-21). Benaron teaches a system for detecting, localizing and targeting a medical instrument toward a target tissue by means of a rectal probe (column 18 lines 51-56) or endoscopes (column 19 lines 6-10). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to design the imaging apparatus taught by Liebig as a rectal probe or as an endoscope probe as a person of ordinary skill has good reason to pursue the known options within his or her technical grasp, and Benaron teaches that an object of the device is to enhance localization by combining both structural and biochemical images simultaneously (column 5 lines 33-46), such as is accomplished by Liebig.

Regarding **claim 23**, Liebig teaches an imaging apparatus according to claim 1 as discussed above. Liebig does not teach the imaging apparatus comprising an intracorporeal portion. Liebig does acknowledge that the technique of coregistered images may be applied to any types of views obtaining using medical imaging techniques (column 12 lines 19-21). Benaron teaches a system for detecting, localizing and targeting a medical instrument toward a target tissue by means of a rectal probe (column 18 lines 51-56). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include an intracorporeal portion in the design of the imaging apparatus taught by Liebig, since Benaron teaches that the closer the imager can get to the portion being imaged the as a rectal probe or as an endoscope probe as a person of ordinary skill has good reason to pursue the known options within his or her technical grasp, and Benaron teaches that an object of the device is to enhance localization by

combining both structural and biochemical images simultaneously (column 5 lines 33-46) and teaches that it is an advantage to monitor more than one modality at a time (column 7 lines 54-58) such as is accomplished by Liebig.

Regarding **claim 24**, the disclosures of Liebig and Benaron teach the rectal probe of claim 23, further comprising movable collimators, operative as vents (Benaron column 10 lines 16-19).

Regarding **claim 25**, the disclosures of Liebig and Benaron teach the rectal probe of claim 23, wherein said motor

13. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Liebig** as applied to claim 1 above, and further in view of **Funda et al. US 5,5722,999 (henceforth referred to as Funda)**.

Regarding **claim 19**, Liebig teaches the imaging apparatus of claim 1, but does not specifically detail the apparatus designed to be mounted on a resectoscope. Liebig does acknowledge that the technique of coregistered images may be applied to any types of views obtaining using medical imaging techniques (column 12 lines 19-21). Funda teaches using the data from preoperative medical images such as CT or MRI in order to pre-program a specialized robotic device for stepping a resectoscope through a sequence (column 1 lines 51-64). It would have been obvious to one of ordinary skill in the art at the time the invention was made to mount the apparatus taught by Liebig on a resectoscope since the images provided by Liebig are multi-

modal and coregistered providing a more defined image for the control of the robotics of the resectoscope, as taught by Funda, and thus provide more accurate incisions.

14. **Claims 20 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Liebig** as applied to claim 1 above, and further in view of **Sieben et al. US 5,243,988 (henceforth referred to as Sieben)**.

Regarding **claims 20 and 21**, the disclosure of Liebig teaches all of the limitations of the imaging apparatus of claim 1, as discussed above. Liebig does not directly disclose the scenario of the imaging system is designed to be inserted in a catheter, or designed for intravascular imaging, however in the art of medical imaging these modifications are common. Liebig does acknowledge that the technique of coregistered images may be applied to any types of views obtaining using medical imaging techniques (column 12 lines 19-21). Sieben for example teaches a medical imaging system designed to be inserted in a catheter or designed for intravascular imaging. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the imaging apparatus taught by Liebig in order to be inserted in a catheter and intravascular imaging as taught by Sieben since a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.

15. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Liebig and Benaron** as applied to claim 23 above, and further in view of **Fry et al. US 4,951,653 (henceforth referred to as Fry)**.

Regarding **claim 26**, the disclosures of Liebig and Benaron teach the rectal probe of claim 23, but does not specifically detail the embodiment further comprising an ultrasound transducer operative of focused ablation. Liebig does acknowledge that the technique of coregistered images may be applied to any types of views obtaining using medical imaging techniques (column 12 lines 19-21). Fry teaches an ultrasound brain lesioning system that uses transducer **29** for focused ablation (column 8 lines 14-19). The apparatus taught by Fry uses ultrasound, CT or MRI scans in order to obtain the feature data of a target, in this case a brain tumor, to accurately control the mechanical drive of the transducer (column 4 lines 18-21). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ultrasound transducer with the coordinate medical imaging taught by Liebig, as Liebig provides coregistered images from a variety of sources such as SPECT, CT and MRI, thus generating a more accurate scan data that Fry acknowledges is desirable with the ultrasound transducer (column 2 lines 2-10).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Maurer, Jr et al. US 6,560,354 B1 teaches an apparatus and method for coregistering images from different modalities, but does not predate the effective filing date of the present application.

Nields et al. US 6,459,925 B1 teaches a user interface system for mammography that uses a coordinate system conducive for coregistering images, but does not predate the effective filing date of the present application.

Cheng et al. US 6,438,401 B1 teaches an imaging system and method that uses imaging data from a fluoroscopic x-ray scan and ultrasound to determine the location of radioactive seeds in a prostate, but does not predate the effective filing date of the present application.

Tanaka et al. US 6,480,732 B1 teaches an image processing device for producing a composite three dimensional image, but does not predate the effective filing date of the present application.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JESSICA L. ELEY whose telephone number is (571)272-9793. The examiner can normally be reached on Monday - Thursday 8:00-6:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Porta can be reached on (571) 272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Constantine Hannaher/
Primary Examiner, Art Unit 2884

/J. L. E./
Examiner, Art Unit 2884